4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2306]

TG United, Inc., et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* of January 15, 2021. The document announced the withdrawal of approval of 27 abbreviated new drug applications (ANDAs) from multiple applicants as of February 16, 2021. The document indicated that FDA was withdrawing approval of the following three ANDAs after receiving a withdrawal request from Upsher-Smith Laboratories, LLC., 6701 Evenstad Dr., Maple Grove, MN 55369: ANDA 084041, Chlordiazepoxide Hydrochloride (HCl) Capsules, 10 milligrams (mg); ANDA 084678, Chlordiazepoxide HCl Capsules, 5 mg; and ANDA 084679, Chlordiazepoxide HCl Capsules, 25 mg. Before FDA withdrew the approval of these ANDAs, Upsher-Smith Laboratories, LLC., informed FDA that it did not want the approval of the ANDAs withdrawn. Because Upsher-Smith Laboratories, LLC., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 084041, 084678, and 084679 is still in effect. In addition, the document indicated that FDA was withdrawing approval of ANDA 206061, Pravastatin Sodium Tablets, 20 mg, 40 mg, and 80 mg, after receiving a request from Hisun Pharmaceutical (Hangzhou) Co., Ltd. However, the document published with the incorrect applicant name for ANDA 206061. This document corrects that error. All other information for ANDA 206061 remains the same.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Friday, January 15, 2021 (86 FR 4081), appearing on page 4081 in FR Doc. 2021-00833, the following corrections are made on page 4082 in the table:

1. The entries for ANDAs 084041, 084678, and 084679 are removed.

2. In the third column, third item from the bottom, the applicant name "Hisun Pharmaceuticals USA, Inc." is corrected to read "Hisun Pharmaceuticals USA, Inc., U.S. Agent for Hisun Pharmaceutical (Hangzhou) Co., Ltd." for ANDA 206061.

Dated: March 29, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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